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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,899	04/27/2007	Jean-Charles Schwartz	P08977US00/BAS	8912

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,899	SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-28-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Response filed November 3, 2008 to the Election of Species Requirement mailed October 2, 2008 is acknowledged. Upon reconsideration, the Election Requirement is withdrawn.

A Preliminary Amendment filed July 28, 2006 is further acknowledged in which claims 1-19 are presented. Claims 1-19 represent all of the claims under consideration. All claims are drawn to the combination of an anti-emetic agent with an enkephalinase inhibitor and are pharmaceutical composition claims.

An Information Disclosure Statement filed July 28, 2006 is further acknowledged and has been reviewed to the extent each reference has been provided.

A complete listing of all related and co-pending applications encompassing enkephalinase inhibitors for the inventors Jean-Charles Schwartz and Jeanne-Marie Lecomte is requested when responding to this Office Action.

Claims 6 and 9-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 14-19 provide for the use of the combination of an anti-emetic agent with an enkephalinase inhibitor, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 6 lacks clarity in that a combination of agents may be administered separately, simultaneously or sequentially, but a composition is a discrete entity. Its components may only be administered together.

Claims 9-12 are indefinite because factors such as modes of administration, body weight, dosage forms, and renal and hepatic status, must be considered when formulating a dosage form. The metes and bounds of the recitation "corresponding doses according to body weight for children and babies" cannot be precisely determined.

Claim 13 appears to be directed to a unit dosage formulation. As such, the recitations "of the invention" and "same" have no probative value in the claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stroppolo et al., US 2004/0115258, in view of Boige et al., Bulletin du Cancer.

Stroppolo teaches pharmaceutical compositions in which a plurality of active ingredients may be blended with cyclodextrin. See paragraph [0122] on page 12. Anti-

emetics, such as granisetron and ondansetron, and an anti-diarrheal, such as acetorphan, may be combined. See paragraphs [0046] and [0050] on page 3.

Motivation to combine an anti-emetic and an anti-diarrheal is provided by Boige, a document that is drawn to digestive complications of cancer chemotherapy. See the discussions under **Prevention et traitement specifiques** and **Diarrhee**. Nausea, vomiting and diarrhea frequently occur following the administration of various cancer chemotherapeutic agents and regimens. Boige teaches an oral dosage of granisetron to be 1 mg every 12 hours, an oral dosage of ondansetron to be 8 mg every 8 hours and an intravenous dosage of ondansetron to be 32 mg. Additionally, dosages based on mg/kg body weight are provided. The specific enkephalinase inhibitor acetorphan, which is racecadotril, at a dosage of 300 mg/day, is specifically indicated in late-onset diarrhea.

Thus, one skilled in the gastroenterology or oncology art would have been motivated to prepare a pharmaceutical composition in which an anti-emetic and an enkephalinase inhibitor are combined. Stroppolo suggests a therapeutic formulation in which such drugs are combined. In the absence of evidence to the contrary, the combination would have been obvious because clear motivation is provided by Boige to administer such agents to treat or prevent nausea, vomiting and diarrhea that often follow the administration of cancer chemotherapeutic agents.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 21, 2008 /Phyllis G. Spivack/

Primary Examiner, Art Unit 1614